

"useful, concrete, and tangible result," namely, the volume of fluid in the peritoneal cavity of a subject, e.g., a subject undergoing peritoneal dialysis, in the case of Claims 34 and 37, or the calculation of a subject-specific calibration constant for use in calculating peritoneal cavity volumes, in the case of Claims 35-36 and 38-39.

Thus, Claim 34 calls for a computer usable medium (e.g., an optical disc; see page 13, lines 23-25, of applicants' specification) having computer readable code means embodied therein (e.g., a VISUAL BASIC computer program; see page 13, lines 19-21, of applicants' specification) for performing step (j) of independent method Claim 1, while Claim 37 calls for a computer which has been programmed to perform that step (e.g., a personal computer configured to run a VISUAL BASIC program; see page 13, lines 21-22, of applicants' specification). Step (j) of Claim 1, referred to in these claims, reads as follows:

- (j) determining the volume V of fluid in the peritoneal cavity  
[of the subject] based on the equation:

$$V = (K_P/\sigma) \bullet (L_P^2/R)$$

where:

- (1)  $K_P$  is a subject-specific calibration constant;
- (2)  $\sigma$  is the conductivity of the fluid in the peritoneal cavity;
- (3)  $L_P$  is the distance between the loin plane and the buttock plane; and
- (4) R is the average of  $R_L$  and  $R_R$ , where

$$R_L = \Phi_L/I, \text{ and}$$

$$R_R = \Phi_R/I.$$

As to Claims 35-36, these claims are directed to a computer usable medium having computer readable code means embodied therein for calculating the subject-specific calibration constant  $K_P$  of the above equation. Claims 38-39 are the corresponding programmed computer claims. As a representative example, Claim 35 calls for "a computer usable medium having computer readable code means embodied therein for performing step (iii) of Claim 2." Step (iii) of Claim 2 reads:

(iii) determining  $K_P$  from the equation:

$$K_P = (\sigma_C) \bullet (V_C/L_P^2) \bullet (R_B R_A)/(R_B - R_A)$$

where

$$R_B = (\Phi_{LB} + \Phi_{RB})/(2I), \text{ and}$$

$$R_A = (\Phi_{LA} + \Phi_{RA})/(2I).$$

Subsequent to the issuance of the September 23<sup>rd</sup> Office Action, the Patent and Trademark Office issued its "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility," which are dated October 26, 2005. The opening paragraph of these guidelines summarizes the state of the law as follows:

In the mid-1990's, the USPTO sought to clarify the legal requirements for statutory subject matter with regard to computer-related inventions. See Examination Guidelines for Computer Related Inventions, 61 Fed. Reg. 7478 (1996). Subsequent to the publication of those guidelines, the Court of Appeals for the Federal Circuit issued opinions in State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F. 3d 1368, 47 USPQ2d 1596 (Fed. Cir. 1998) and AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 50 USPQ2d 1447 (Fed. Cir. 1999). These decisions explained that, to be eligible for patent protection, the claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." State Street, 149 F.3d at 1373-74, 47 USPQ2d at 1601-02....

Applicants respectfully submit that their Claims 34-39 fully satisfy the "useful, concrete, and tangible result" standard of the State Street and AT&T cases cited in this passage.

Beginning with State Street, Claim 1 of the patent involved in that case read:

1. A data processing system for managing a financial services configuration of a portfolio established as a partnership, each partner being one of a plurality of funds, comprising:

- (a) computer processor means for processing data;
- (b) storage means for storing data on a storage medium;
- (c) first means for initializing the storage medium;

(d) second means for processing data regarding assets in the portfolio and each of the funds from a previous day and data regarding increases or decreases in each of the funds, [sic, funds'] assets and for allocating the percentage share that each fund holds in the portfolio;

(e) third means for processing data regarding daily incremental income, expenses, and net realized gain or loss for the portfolio and for allocating such data among each fund;

(f) fourth means for processing data regarding daily net unrealized gain or loss for the portfolio and for allocating such data among each fund; and

(g) fifth means for processing data regarding aggregate year-end income, expenses, and capital gain or loss for the portfolio and each of the funds. (U.S. Patent No. 5,193,056)

In finding that this claim satisfied the requirements of §101, the CAFC wrote:

Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete and tangible result" -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades. (State Street, 44 USPQ2d at 1601.)

In AT&T, the CAFC specifically relied on this basic methodology set forth in State Street:

In State Street, we held that the processing system there was patentable subject matter because the system takes data representing discrete dollar amounts through a series of mathematical calculations to determine a final share price -- a useful, concrete, and tangible result. See 149 F.3d at 1373, 47 USPQ2d at 1601. (AT&T, 50 USPQ2d at 1452.)

When this methodology is applied to the claims of the present invention, the conclusion is inescapable that applicants' claims satisfy the requirements of §101.

Thus, in State Street, the data in question "represent[ed] discrete dollar amounts." Here, the data in question represents conductivity ( $\sigma$  and  $\sigma_C$ ), distance ( $L_P$ ),

volume ( $V_C$ ), voltage ( $\Phi_L$ ,  $\Phi_R$ ,  $\Phi_{LB}$ ,  $\Phi_{RB}$ ,  $\Phi_{LA}$ , and  $\Phi_{RA}$ ) and current ( $I$ ). In State Street, mathematical calculations were used to determine a "final share price." Here, mathematical calculations are used to determine a "volume  $V$  of fluid in the peritoneal cavity" of a subject (Claims 34 and 37) or a "subject-specific calibration constant"  $K_p$  (Claims 35-36 and 38-39).

In State Street, the final share prices constituted a "useful, concrete, and tangible result" thus entitling Signature Financial Group, the assignee of the patent involved in State Street, to patent protection under §101. Plainly, if the calculation of a "final share price" qualifies as a "useful, concrete, and tangible result," then so too should the calculation of a subject's peritoneal volume or the calculation of a subject-specific calibration constant for use in calculating a peritoneal volume. Certainly, a person undergoing peritoneal dialysis would think so. Indeed, if asked during such a procedure if peritoneal volume or a final share price was more useful, concrete, and tangible, one might guess that the person being dialyzed (as well as those administering the procedure) might at the moment, pick peritoneal volume.

In sum, applicants respectfully submit that under the applicable authorities, Claims 34-39 fully satisfy the requirements of 35 USC §101. Accordingly, reconsideration, withdrawal of the §101 rejection, and the issuance of a notice of allowance for this application are respectfully requested.

Respectfully submitted,

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